Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

Updated April 30, 2003

Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

Contents

Part I – Overview of MDUFMA

Background

- Developed in consultation with industry, user groups, and consumer groups.
- Bipartisan House and Senate support (with some challenging compromises).
- Explicitly recognizes need for additional medical device resources.
- Signed into law October 26, 2002; enabling appropriations signed February 20, 2003.

Key Provisions of MDUFMA

- Medical device user fees and additional appropriations.
- Third-party establishment inspections.
- Greater oversight of reprocessed single-use devices.
- Electronic labeling.
- Modular review.
- FDA-OC oversight of combination products.

Medical Device User Fees

- Fees for PMAs, PDPs, BLAs, premarket reports (PMA for a reprocessed single-use device), certain supplements, 510(k)s.
- $25.1 million in fee revenues during FY 2003, rising to $35 million in FY 2007 (plus adjustments).
- Plus $15 million additional appropriations, brings total new resources to $40.1 million for FY 2003, rising to $50+ by FY 2007.

User Fees (con't)

- First year fees range from $154,000 for a premarket application, to $2,187 for a 510(k).
- Reduced fees to protect small businesses ("small" = receipts and sales # $30 million).
- Small business fees are in effect for FY 2003, except reduced fee for 510(k) starts FY 2004.
- Sunset October 1, 2007. (Earlier, if appropriations do not meet certain levels.)

Fee Exemptions, Waivers

- No fee if applicant is Federal or State government, unless device is to be marketed.
- First premarket application by a small business is free.
- Premarket report by holder of PMA for the same reprocessed device is free.
- No fee for third-party 510(k).
- No fee for Humanitarian Device Exemption.

Fee Exemptions, Waivers (con't)

- No fee for any application intended solely for pediatric use.
- No fee for other submissions:
  - No fee for Investigational Device Exemption.
  - No fee for Master File or Annual Report.
  - No fee for 30-day Notice (PMA Supplement concerning modifications to manufacturing procedures or method of manufacture).
  - No fee for 135-day PMA Supplement (required when FDA finds 30-day Notice inadequate).

Third-Party Inspections

- Most complex, strict, potentially confusing provisions of the new law.
- FDA-accredited third-party may inspect a manufacturer of class II and class III devices if strict eligibility requirements are met by the establishment and the selected third-party.

Third-Party Inspections (con't)

- FDA must publish accreditation criteria by April 24, 2003.
- FDA must accredit third-parties by October 26, 2003.
- No more than 15 third-parties permitted in first year of program.

Third-Party Inspections (con't)

- Strict conflict of interest provisions restrict third-parties, prevent affiliation, consultation with establishments.
- FDA must conduct periodic audits to ensure accredited persons "continue to meet the standards of accreditation."
- Sunset October 1, 2012.

Restrictions on Use of Third-Parties

- Establishment markets in U.S. and abroad.
- Most-recent FDA inspection must have been classified as NAI or VAI.
- FDA must clear use of selected third-party.
- Third-party and FDA inspections must be acceptable abroad.
- FDA must periodically inspect (1 of 3).
- No effect on MRA, other agreements.

Reprocessed Single-Use Devices

- Reprocessed single-use devices must be labeled as such, and reprocessor identified.
- New submission type: premarket report – variant of PMA for a reprocessed device.
- By April 26, 2003, FDA must identify types of reprocessed devices that must provide validation data in future 510(k)s.

Reprocessed Devices (con't)

- Validation data for those reprocessed devices that already have a 510(k) will be required by January 26, 2004.
- FDA is to reconsider existing exemptions from 510(k) for certain reprocessed devices—
  - critical devices by April 26, 2003
  - semi-critical devices by April 26, 2004.

Device Labeling Provisions

- Electronic labeling permitted when—
  - Prescription device.
  - Intended for use in a health care facility.
  - Labeling complies with all other requirements of law.
  - Traditional paper labeling must be "promptly" provided to the health care facility without additional cost.

Device Labeling Provisions (con't)

- Manufacturer of a device must be identified on the device, with exceptions.

Postmarket Surveillance

- Authorizes additional appropriations for medical device postmarket surveillance: $3 million for FY 2003, $6 million for FY 2004, more later. (Authorization does not ensure appropriation. No additional funds were appropriated for FY 2003.)
- FDA must report on effects of user fee program on postmarket surveillance, identify needs, by January 10, 2007.

Wait! There's More!

- Third-party 510(k) review – new sunset: October 1, 2007.
- Combination products – reviews coordinated by new Office of Combination Products in the Office of Commissioner.
- Electronic registration – when feasible.

And more!

- FD&C §513(i)(1)(E) (intended use is based on proposed labeling) – now permanent.
- Modular review of PMAs – now in statute.
- New provisions added concerning devices intended for pediatric use.

Part II – User Fees

Guiding Principles

- Industry agrees to pay fees for additional resources that will improve device review.
- Congress agrees to additional appropriations for device review.
- FDA agrees to challenging, measurable performance goals to gauge improvement.

Show Me the Money!

Fee Revenues:

- FY 2003: $25,125,000
- FY 2004: $27,255,000
- FY 2005: $29,785,000
- FY 2006: $32,615,000
- FY 2007: $35,000,000

Appropriations:

- FY 2003 actual: $2,735,000 (inc. recission)
- FY 2004 and later: $15,000,000

Total new resources:

- $27,860,00 in FY 2003.
- Rising to $50,000,000+ in FY 2007.

How Can FDA Use Fees?

"Process for the review of device applications"

- Staff training
- New FDA staff
- Outside expertise
- Guidance and standards development
- Classification and reclassification
- Panel meetings
- Preapproval inspections
- Review of postmarket condition studies
- Review of postmarket data, when applicable
- IT Support

Reviews Subject to User Fees

- Effective October 1, 2002, a user fee is assessed for FDA review of a—
  - 510(k)
  - Premarket application — PMA (including a modular submission), PDP, Premarket Report (reprocessed device), or BLA.
  - Panel-track supplement
  - 180-day supplement
  - Real-time supplement
  - BLA efficacy supplement

Standard Fees

- PMA, PDP, premarket report, BLA, panel-track supplement, BLA efficacy supplement all pay the same fee. This fee provides the base for other fees.
- 180-day supplement – 21.5% of base fee.
- Real-time supplement – 7.2% of base fee.
- 510(k) – 1.42% of base fee.

Reduced Fees Protect Small Business

- A small business is one with gross receipts or sales #$30 million (including all affiliates, partners, and parent firms).
- Small business status must be evidenced by submission of Federal Income Tax returns.
- Small business fees are 38% of standard fee, except 510(k) is 80% of standard fee.
- 510(k) small business fee begins FY 2004.

Explicit Fee Exceptions

No fee for—

- Humanitarian Device Exemption.
- BLA supplement for further manufacturing use.
- First premarket application (PMA, PDP, BLA, or premarket report) from a small business.
- Premarket report by holder of PMA for same reprocessed device.
- Third-party 510(k).
- Any application from a State or Federal Government entity.
- Any application intended solely for pediatric use.

Fee Exception for Pediatric Devices

- No fee for any application intended solely for pediatric use.
- If the holder of a premarket application for a pediatric device obtained a fee waiver (did not pay a fee), and later submits a supplement that proposes a use for any adult population, the fee due is the fee then in effect for a premarket application.

Implicit Fee Exceptions

No fee for any submission unless it is specifically identified as subject to a fee. Thus, no fee for—

- Investigational Device Exemption
- 30-day Notice
- 135-day Supplement
- Special PMA Supp.
- Express PMA Supp.
- Annual Report
- BLA Resubmission
- BLA Efficacy Supplement Resubmission
- Anything else unless law says fee is required.

First-Year Fees (FY 2003)

Application	Standard Fee	Small Business Fee
• PMA, PDP, BLA, Premarket report, Panel-track supplement, BLA efficacy supplement	$154,000	$58,520
• 180-day supplement	$33,110	$12,582
• Real-time supplement	$11,088	$4,213
• 510(k)	$2,187	$2,187†

†A reduced small business fee for 510(k)s will be available beginning with FY 2004 submissions.

Annual Adjustments to Fees

- Each FY, FDA may revise user fees to reflect—
  - Inflation (measured by CPI or pay raises).
  - Changes in workloads (all submissions).
  - Revenue shortfalls from previous years.
- New fees will be announced in the Federal Register around August 1 of each year.

Payment of Fees

- Beginning April 1, 2003, if an application is subject to a user fee, the fee must be paid at the time the application is submitted to FDA.
- Modular PMA – full fee due with first module.
- If fee not paid, application "shall be considered incomplete and shall not be accepted for filing."
- FDA will send invoices for fees due for submissions received during transition period (October 1, 2002 to April 1, 2003).

Refunds

- 510(k) fee: No refunds.
- All other fees: Make written request within 180 days. Refund amounts:
  - FDA refused to file – 75% of fee.
  - Applicant withdraws submission prior to FDA filing decision – 75% of fee.
  - Applicant withdraws after filing, but before a first action – refund of any part of a fee at FDA's discretion, based on effort expended.
  - After first action – No refund.

Part III – Performance Goals

Guiding Principles

- More predictable, more timely reviews will lead to earlier availability of safe and effective devices.
- Progressive performance goals will demonstrate added resources are improving device review process.

Performance Goals

- MDUFMA requires FDA to meet challenging performance goals for each type of submission.
- Goals are defined in letter from DHHS Secretary Thompson to Congress.
- Cycle and decision goals.
- Goals become more aggressive over time. FDA must show continual improvement.

Performance Goals (con't)

- Overall, aiming to improve performance by 25%, even more for breakthrough devices.
- If appropriations do not meet certain levels, FDA is "expected to meet such goals to the extent practicable . . ."
- Beginning FY 2006, if appropriations fall short, user fees cannot be collected and FDA is not expected to meet goals.

Performance Goals for PMAs, PDPs, Premarket Reports, and Panel-Track Supplements

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal)				
		2003	2004	2005	2006	2007
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	–	–	–	80%	90%
• FDA decision – median performance	180 days	–	–	–	–	50%
• First action – "major deficiency" letter	150 days	–	–	75%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	–	–	75%	80%	90%
• Second or later action – "major deficiency" letter	120 days	–	–	75%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	–	–	75%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%

Performance Goals for PMAs, PDPs, Premarket Reports, and Panel-Track Supplements (con't)

- FY 2007 performance goal calling for 50% of premarket applications to have an FDA decision within 180 days will be re-evaluated during FY 2006.
- FDA will hold a public meeting, consult with stakeholders.
- FDA must notify Congress by August 1, 2006 if goal is not appropriate.

Performance Goals for Expedited PMAs

These goals apply only when all of these conditions have been met—

- FDA has granted expedited status.
- The applicant has attended a pre-filing review meeting.
- Manufacturing facilities are ready for inspection when the PMA is submitted.
- The PMA is substantively complete.

Performance Goals for Expedited PMAs (con't)

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal) 2003	2004	2005	2006	2007
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	–	–	70%	80%	90%
• First action – "major deficiency" letter	120 days	–	–	70%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	–	–	70%	80%	90%
• Second or later action – "major deficiency" letter	100 days	–	–	70%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	–	–	70%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%

Performance Goals for 180-day PMA Supplements

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal)				
		2003	2004	2005	2006	2007
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	–	–	80%	85%	90%
• First action – "not approvable" letter	120 days	–	–	80%	85%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	–	–	80%	85%	90%
Action on an amendment containing a complete response to a "not approvable" letter	160 days	–	–	80%	85%	90%

Performance Goals for Real-Time PMA Supplements

- FDA will maintain current performance.

Performance Goals for 510(k)s

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal) 2003	2004	2005	2006	2007
• FDA decision (SE/NSE)	90 days	–	–	75%	75%	80%
• First action – "additional information" letter	75 days	–	–	70%	80%	90%
• Second or later action	60 days	–	–	70%	80%	90%

- FY 2007 FDA decision goal calling for 80% of 510(k) SE/NSE decisions to be made within 90 days will be re-evaluated during FY 2006.

Performance Goals for BLAs

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal)				
		2003	2004	2005	2006	2007
• Review and act on standard original BLA submissions	10 months	–	–	–	75%	90%
• Review and act on priority original BLA submissions	6 months	–	–	–	75%	90%

- "Review and act on" means issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

Performance Goals for BLA Efficacy Supplements

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal)				
		2003	2004	2005	2006	2007
• Review and act on standard original BLA efficacy supplement submissions	10 months	–	–	–	75%	90%
• Review and act on priority original BLA efficacy supplement submissions	6 months	–	–	–	75%	90%

- "Review and act on" means issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

Performance Goals for Original BLA Resubmissions and BLA Efficacy Supplement Resubmission

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal) 2003	2004	2005	2006	2007
• Review and act on class 1 original BLA resubmissions and class I BLA efficacy supplement resubmissions	2 months	–	–	75%	80%	90%
• Review and act on class 2 original BLA resubmissions and class I BLA efficacy supplement resubmissions	6 months	–	–	75%	80%	90%

Class 1 vs. Class 2 Resubmissions

Class 1 resubmission – an application resubmitted after a complete response letter that includes only the following:

- Final printed labeling.
- Draft labeling.
- Safety updates submitted in the same format (except large amounts of new information).
- Stability updates to support provisional or final dating periods.
- Commitments to perform Phase 4 studies, including proposals for such studies.
- Assay validation data.
- Final release testing on the last 1-2 lots used to support approval.
- A minor reanalysis of data previously submitted to the application.
- Other minor clarifying information.
- Other specific items may be added later as the Agency gains experience.

Class 2 resubmission – a resubmission that includes any other item.

Performance Goals for BLA Manufacturing Supplements Requiring Prior Approval

Activity	Review Time	Performance Level (by FY) (– indicates no quantitative goal)				
		2003	2004	2005	2006	2007
• Review and act on BLA manufacturing supplements requiring prior approval	4 months	–	–	–	75%	90%

- "Review and act on" means issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

Additional Performance Goals

- Current performance will be maintained in review areas that do no have quantitative performance goals.
- Greater use of meetings with industry (both formal and informal meetings).
- Significant user fee revenues will be used for reviewer training and hiring, including use of outside contracting, to achieve goals.

Additional Performance Goals

- FDA will issue guidance regarding modular PMAs under new §515(c)(3).
- FDA will consult with stakeholders to develop performance goals for modular PMA reviews.
- FDA will consult with stakeholders and determine an appropriate "bundling" policy.

Additional Performance Goals

- FDA will continue its efforts to develop systems for the electronic reviews.
- FDA will work to improve the scheduling and timeliness of preapproval inspections, and will report on our progress.
- Beginning in FY 2004, FDA will hold an annual public meeting to review progress in implementing MDUFMA.

Part IV – Third-Party Inspections

Third-Party Inspections

- Most complex, strict, potentially confusing provisions of the new law.
- FDA-accredited third-party may inspect a manufacturer of class II and class III devices if strict eligibility requirements are met by the establishment and the selected third-party.
- Inspections permitted are QS/GMP only. Pre-approval, BIMO, and "for cause" inspections remain exclusive FDA purview.

Third-Party Inspections (con't)

- Establishment negotiates fee, pays for inspection (not funded by FDA).
- Very strict conflict of interest provisions.
- Sunset October 1, 2012.
- No effect on MRA, other agreements.

Accredited Persons

- FDA must publish accreditation criteria by April 24, 2003.
- FDA must accredit third-parties by October 26, 2003.
- FDA is permitted to accredit no more than 15 third-parties for the first year of program.

Minimum Requirements for Accreditation

- Cannot be employee of Federal government.
- Must be independent—
  - Not owned or controlled by a manufacturer, supplier, vendor of any article regulated by FDA.
  - No organizational, material, or financial affiliation with a manufacturer, supplier, or vendor.
  - No consultative affiliation with a manufacturer, supplier, or vendor.

Minimum Requirements for Accreditation (con't)

- Cannot design, manufacture, promote, or sell any article regulated by FDA.
- Must agree in writing to –
  - Certify the accuracy of information reported to FDA.
  - Limit work to areas where competent.
  - Treat all information as confidential commercial or trade secret.
  - Promptly respond to, resolve, complaints.
  - Protect against employee conflict of interest.

FDA Responsibilities

- Web site will list currently accredited persons.
- Periodic audits of accredited persons.
- Approve each use of a third-party inspection.
- Review each report from third-party inspection.
- FDA may withdraw accreditation if third-party is not in compliance with FDA requirements, poses a threat to public health, or fails to act in manner consistent with purposes of program.

Restrictions on Establishment's Use of Third-Parties

- Establishment markets in U.S. and abroad.
- Most-recent FDA inspection must have been classified as NAI or VAI.
- FDA must clear each use of a third-party.
- Third-party and FDA inspections must be acceptable abroad.
- FDA must periodically inspect (normally, at least one out of three inspections).

Part V — Reprocessed Single-Use Devices

Increased FDA Oversight of Reprocessed Single-Use Devices

- Reprocessed single-use devices must be "prominently and conspicuously" labeled:

  Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].

- More premarket data is required –
  - Class I and II – additional validation data.
  - Class III – New type of premarket submission, the premarket report, with additional data requirements that focus on reprocessing.

Validation Data Now Required for Class I and Class II Devices

- By April 26, 2003, FDA must identify devices for which future 510(k)s must include "validation data . . . regarding cleaning and sterilization, and functional performance" to show device will remain SE after all intended reprocessing.
- If a device identified by FDA already has a 510(k), manufacturer must submit validation data within nine months.

Reconsideration of Exemptions from 510(k)

- FDA must reconsider existing exemptions from 510(k)—
  - Critical reprocessed devices— by April 26, 2003.
  - Semi-critical reprocessed devices— by April 26, 2004.
- If FDA revokes exemption, 510(k) required within 15 months.

Part VI — Additional Provisions

Electronic Labeling

- Electronic labeling (e.g., labeling provided through a WWW site) may be used instead of traditional paper labels if—
  - the device is a prescription device and
  - the device is intended to be used solely in a health care facility.
- The manufacturer must provide traditional printed labeling upon request.

Modular Review of PMAs

- Modular PMA reviews are now in the statute.
- A modular submission (shell and all modules) is subject to the same fee as a standard PMA.
- Payment of the entire fee is required with the first module submitted to FDA.
- FDA must negotiate performance goals.

Pediatric Use

- No fee for any application intended solely for pediatric use. (If supplement proposes a use for any adult population, then full PMA fee is due.)
- FDA must issue guidance on information required to show S&E, and on protection of children in clinical trials.
- Advisory panels must have pediatric expertise, when needed.
- IoM to study postmarket surveillance adequacy.

Additional Provisions

- Third-party 510(k) review – new sunset: October 1, 2007.
- Combination products – reviews will be coordinated by new Office of Combination Products in the Office of the Commissioner.
- Electronic registration – when feasible.

Additional Provisions (con't)

- FD&C § 513(i)(1)(E) (intended use is based upon proposed labeling) – now permanent.
- Manufacturer of a device must be identified on the device, with exceptions
- GAO and NIH are directed to prepare reports concerning breast implants.

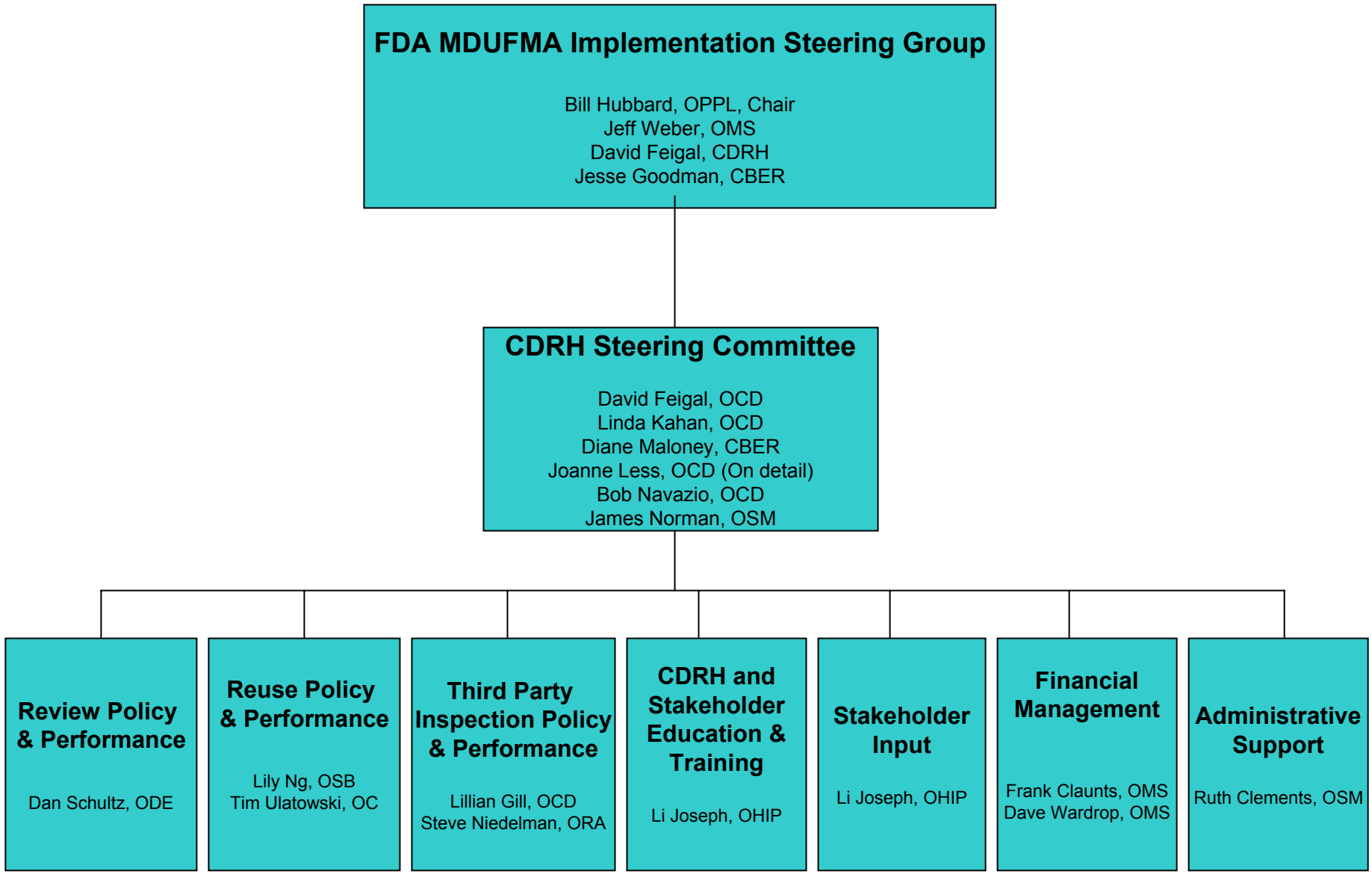
Additional Provisions (con't)

- Authorizes additional appropriations for postmarket surveillance (Congress has not yet enacted these appropriations).
- FDA must report on effect of user fees on postmarket programs.

Part VII – Implementation

First Steps

- Launched an Internet site to provide information to the public (and to FDA): www.fda.gov/oc/mdufma
- Developed and posted essential reference materials:
  - Plain-language summary.
  - FAQs.
  - List of action dates set by law.
  - Guidance documents
- Established an open docket to encourage comments: www.fda.gov/ohrms/dockets/dockets/02n0534/02n0534.htm
- Formed an implementation team, assigned tasks.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Critical Path Issues

- PMA Supplements – Defined the dividing lines between 180-day, panel-track, and real-time supplements.
- Modular PMAs – Determined how to handle modular submissions begun prior to FY 2003.
- Bundling policy – Handling of submissions that affect or involve multiple applications.
- Payment procedures for FY 2003.

PMA Supplement Definitions

Panel-track	180-day	Real-time
New pivotal trial to support— • a new indication for use; or • a change in device design or performance that could significantly affect clinical outcome.	At most, confirmatory clinical data to support significant change in— • principle of operation; • control mechanism; • design or performance; • labeling; or • new testing requirements or acceptance criteria.	• No clinical data or GMP inspection; and • Minor change to device design, labeling (but not a new contraindication), sterilization, or packaging; and • FDA and applicant agree real-time review is appropriate.

See FDA's guidance at www.fda.gov/cdrh/mdufma/guidance/1201.pdf

Modular PMAs

- If you initiated a modular PMA (you actually submitted a module) prior to October 1, 2002, FDA will not assess a fee.
- New modular PMAs – pay full PMA fee at time first module is submitted.
- No fee for shell.
- No filing decision for modules.
- FDA is developing guidance on review timeframes, criteria for closing / re-opening modules, other features unique to modules.

Bundling

- Primary objective: efficient review, timely decision.
- Appropriate when scientific and regulatory issues can be efficiently resolved during the course of one review.
- FDA will not "split out" a device from an appropriate bundle to increase fee revenue.
- Applicants should not bundle unrelated applications in an effort to reduce fees.

FY 2003 Payment Procedures

- FDA continued review of new submissions during transition period — no delay.
- Effective April 1, 2003, fee payment required before application will be filed (no payment = no filing = no review).
- Guidance explains how to qualify for reduced small business fees.
- Applications submitted prior to October 1, 2002 are not subject to a fee.

Now Working on More Issues

- Need to develop comprehensive training plan to ensure reviewers have (and maintain) essential skills and knowledge.
- FDA recognizes requirement for Federal Income Tax return may disadvantage some applicants who believe they should be treated as a small business.
- Need to determine how various types of disputes will be resolved.

Still More Issues

- Need to develop comprehensive training plan to ensure reviewers have/maintain essential skills and knowledge.
- Need improvements to, innovation in review processes – project management, outside consultants, contractors, more.
- Additional guidance – in many areas – must be developed as rapidly as possible.

Guidance Documents

- All MDUFMA guidances are cataloged at www.fda.gov/cdrh/mdufma/guidance
- Guidance documents completed as of April 30, 2003:
  - Assessing User Fees: Definitions (PMA supplements, BLAs, BLA efficacy supplements); modular PMAs; bundling; combination products
  - FY 2003 MDUFMA Small Business Qualification Worksheet and Certification
  - Electronic Labeling for Prescription Devices Intended for Use in Health Care Facilities
  - Criteria for accreditation of third-parties to inspect manufacturers of class II and class III medical devices

Planned Guidance

- 510(k) first actions, decisions
- Appeals
- Bundling
- Electronic labeling
- Expedited PMA
- Identification of device manufacturer
- Modular PMA
- Pediatric indications
- Pediatric panel expertise
- PMA filing
- PMA first actions, decisions
- Reuse validation

For Additional Information . . .

- Visit the MDUFMA web site for guidance, reference materials, and new information:

  www.fda.gov/oc/mdufma

- Guidance documents provide best detail.
- Contact the Division of Small Manufacturers, International, and Consumer Assistance:

  800-638-2041 or 301-443-6597